

### REMARKS

The Office Action mailed on May 21, 2003, made final, has been carefully considered and the Examiner's remarks are appreciated. Claims 1-17 were originally in the application. Claim 3 was previously cancelled, and claims 18-21 were previously added. Therefore claims 1, 2, and 4-21 are presented for examination. Applicants respectfully request reconsideration in view of the following remarks.

#### Brief Discussion of the Invention

As previously discussed in the communication filed on May 8, 2003, the present invention is a porous protective sheath having active extraction media retainably contained therein for use in solid phase microextraction (SPME). The sheath permits exposure of the media to the environment (for sampling and desorption) without having to directly expose (e.g. by extension) a fragile coated fiber outside the sheath and risk breakage or other damage to the fiber, as is often seen in practice. This is possible via perforations along at least a length of the sheath through which a medium to be sampled may enter and exit the sheath and into contact with the active extraction media. Moreover, the sheath, having a sufficient strength and rigidity, is adapted to pierce through a septum such as used in gas chromatographs and other similar devices. In this manner the present invention serves to mitigate such problems as (1) fiber breakage due to fiber extension during sampling and desorption, (2) active media coating loss caused by physical contact of the bare fiber with the sampling environment, and (3) coating slough-off during fiber extension and retraction operations caused by rubbing action between the fiber and a protective needle or tube.

### Discussion of the Rejections Under 35 USC §103(a)

The Examiner rejected claims 1, 2, 4-13, and 15-17 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,164,144 to Berg in view of U.S. Patent 6,042,787 to Pawliszyn, (hereinafter “Pawliszyn-787”). In support of his rejections, the Examiner cited Berg as teaching a SPME device comprising a pointed, open-ended needle 24 having a stationary phase coating 32 along the inner surface of the needle, but which does not disclose a needle formed with holes or perforations along its length. To supply this missing element, the Examiner also cited Pawliszyn-787 for teaching “*a SPME device comprising a member with an extraction coating (reference item 80) that is generally surrounded by a protective sheath (reference item 108)...*”

It is respectfully submitted, however, that the Examiner has failed to make a prima facie case of obviousness as required by MPEP §2143.01, due to the absence of any teaching, suggestion, or incentive/motivation to combine the teachings of the Berg and Pawliszyn-787 references. As stated by the CAFC in In re Mills 916 F.2d 680, “*The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.*” There is nothing in either Berg or Pawliszyn-787 which suggests the desirability of providing the perforations of Pawliszyn-787 along a length of the hollow needle of Berg so as “to enable active extraction media to carry out a solid phase micro-extraction process from within the sheath [porous tube]” (claims 1 and [10]). Berg describes an arrangement where sampling, sample redispensing, and analyte flushing (i.e. a solid phase micro-extraction process) all occur through a single opening at the needle tip 68, whereby sample flow into and out of the needle takes place in a longitudinal direction of the needle. To this end, a plunger 18 aligned with the needle is provided to draw/redispense a sample into and out of the needle tip for analyte adsorption, and a gas supply is provided to desorb and flush out the analytes from the needle tip, e.g. for GC analysis. There is,

however, nothing which suggests the desirability of providing additional transverse flows through the elongated sheath (inherent to the perforations located “along at least a section of length thereof”) and into contact with active extraction media. On the contrary, given the particular arrangement of Berg, perforations along the length of the needle may in fact operate to divert and thereby reduce the flow entering or exiting through the needle tip 68, and consequently reduce the degree of force generated when expelling analytes, for example. Thus, the proposed modification/combination of Berg and Pawliszyn-787 suggested by the Examiner would change the principle of operation of Berg, and the references are therefore not sufficient to render the claims prima facie obvious (*In re Ratt*, 270 F.2d 810).

Additionally, there is also no suggestion of the desirability of providing the stationary phase coating of Berg as an inner lining to the open-ended shield 108 having perforations 110 of Pawliszyn-787. On the contrary, Pawliszyn-787 teaches that it is desirable to retract the extracting surface 80 within a sealed cavity 70 when not in use, and only to extend it into the volume surrounded by the shield 108 for carrying out adsorption and desorption. Pawliszyn-787 also teaches either (1) removal of the perforated tubular shield for cleaning and desorption to expose the fiber, or (2) extension of the fiber beyond the perforated tubular shield for cleaning and desorption in a GC injection port. In either case, Pawliszyn-787 teaches the importance of the independence and severability of the fiber from the shield, and thus teaches away from lining the inner surface of the shield with the fiber. Here too, the proposed modification/combination of Berg and Pawliszyn-787 suggested by the Examiner would therefore also change the principle of operation of Pawliszyn-787. Accordingly, it is respectfully submitted that claims 1 and 10 are allowable as previously presented. And it is submitted that the §103(a) rejections of claims 2, 4-9, and 13, 15-17 are also in condition for allowance as being dependent on independent claims 1 and 10, and the rejections being similarly inappropriate in view of MPEP §2143.03.

The Examiner also rejected claims 18-21 under 35 U.S.C. §103(a) as being unpatentable over Berg in view of Pawliszyn-787 and further in view of U.S. Pat. No. 5,693,228 to Koehler et al (hereinafter “Koehler”). In support of his rejection, the Examiner cited Koehler to supply the teaching of “*a needle coated with a loose, particulate material and where the holes are smaller than the grain size fo the particulate material*” not found in Berg or Pawliszyn-787. In particular, the Examiner stated, “*The active coating on the fiber can be comprised of ...graphite... [among others]*” and that “*In the above list graphite is a well-known particulate material.*”

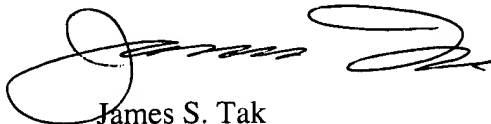
Similar to the communication of May 8, 2003, it is respectfully submitted that the Examiner is incorrect in his reading and determination that the reference to graphite in Koehler describes or suggests a “loose particulate composition,” as required in claims 18 and 20. As described in column 4, lines 39-50, the fiber and choice of fiber is described as a coating, and not a particulate, loose or otherwise. Furthermore, as described in column 4, lines 26-31 of Koehler, “*Fiber 46 is partially enclosed within metal casing 57 which surrounds that portion of the fiber 46 located within the plunger 52, barrel 50 and part of the needle 44*” (emphasis added). Consequently, this exposed configuration of the fiber cannot reasonably support or retainably contain the loose graphite particles. This is reinforced by Figure 2A of Koehler showing the fiber 46 as a solid thread-like material, without any means of retaining fiber other than on its outer surface. Thus, notwithstanding the Examiner’s assertion to the contrary, there is no teaching or suggestion of providing active extraction media having a loose particulate composition. Accordingly, it is respectfully submitted that claims 18-21 are allowable as previously presented.

#### Summary

Applicants therefore respectfully submit that claims 1, 2, 4-21 are in condition for allowance, and requests allowance of claims 1, 2, 4-21. In the event that the Examiner finds any remaining

impediment to the prompt allowance of these claims that could be clarified with a telephone conference,  
he is respectfully requested to initiate the same with the undersigned at (925) 422-7274.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'James S. Tak', with a large, stylized initial 'J'.

Dated: November 21, 2003

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